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Protalix BioTherapeutics, Inc. (PLX: NYSE)

PLX: More Regulatory Approvals

The valuation employs a net present value (NPV) approach and a 15% discount rate. Our model recognizes Elfabrio's approval in Fabry Disease in the United States and the EU and assigns 100% probability of success to it and Elelyso following US and European approval. The model includes contributions from global commercialization.

Current Price (11/6/2023)	$1.51
Valuation	**$16.00**

OUTLOOK

Protalix is a clinical and commercial pharmaceutical company using its proprietary ProCellEx plant-based expression system to produce therapeutic proteins for global markets. The company has two commercialized products, Elelyso that is marketed by Fiocruz in Brazil & Pfizer in the rest of the world for Gaucher Disease and Elfabrio which was approved in May 2023. Chiesi Rare Disease will commercialize Elfabrio globally.

Protalix has additional candidates in earlier stages of development including PRX-115 for the treatment of refractory gout and PRX-119, a long action DNase I for the treatment of NETs-related diseases.

Elfabrio was approved in Europe and the United States in early May 2023. The product can fill an unmet need with several improvements over the market leader and is expected to command a premium vs. existing products. Elelyso should show moderate growth over the next quarters as partners continue their commercialization efforts. Profits from revenue generating products are expected to be invested in new candidates in coming years.

SUMMARY DATA

52-Week High	**$3.55**
52-Week Low	**$1.00**
One-Year Return (%)	**46.6**
Beta	**1.3**
Average Daily Volume (sh)	**508,304**
Shares Outstanding (mil)	**73.0**
Market Capitalization ($mil)	**110.2**
Short Interest Ratio (days)	**14.2**
Institutional Ownership (%)	**6.7**
Insider Ownership (%)	**9.6**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**126**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2023 Estimate	**28.0**
P/E using 2024 Estimate	**7.2**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of USD)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	$16.1 A	$8.8 A	$14.2 A	$8.6 A	$47.6 A
2023	$9.6 A	$35.1 A	$10.3 A	$10.5 E	$65.5 E
2024					$74.1 E
2025					$127.4 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	-$0.05 A	-$0.11 A	-$0.07 A	-$0.07 A	-$0.31 A
2023	-$0.05 A	$0.21 A	-$0.02 A	-$0.02 E	$0.05 E
2024					$0.21 E
2025					$0.81 E

WHAT'S NEW

Third Quarter 2023 Financial and Operational Review

Protalix Biotherapeutics, Inc. (NYSE: PLX) announced 3Q:23 financial and operational results in a November 6th, 2023 press release and filing of Form 10-Q. The reports were followed by a conference call which discussed recent achievements, regulatory updates and financial performance. Since the end of the second quarter, company management and stakeholders have participated in investor and scientific conferences, a new Chairman of the Board of Directors has been appointed, and Protalix' partner, Chiesi Rare Disease, has continued to ramp up Elfabrio sales and obtain approval in additional jurisdictions.

Revenues for 3Q:23 were $10.3 million, which consisted of $5.5 million from Chiesi, $2.3 million from Fiocruz and $2.3 million in revenues from Pfizer. This produced a net loss of ($1.9) million in the most recent quarter versus a net loss of ($3.6) million in 3Q:22.

Financial results for the quarter ending September 30, 2023, compared to prior year comparable period:

- Revenues were $10.3 million, down 27% from $14.2 million; as lower license and R&D revenues were only partially offset by an increase in product revenues. Pfizer sales were down 49% to $3.4 million, Fiocruz sales were up 36% to $2.3 million and Chiesi sales were up 116% to $5.5 million;
- Cost of revenue was down 31% to $4.9 million as higher gross margin from Elfabrio more than offset lower Elelyso margins and sales from lower margin Elelyso declined. This mix produced a 52% gross margin on goods sold which surpassed the 20% gross margin in the comparison period;
- Research and development expenses fell 50% to $3.7 million from $7.4 million. Substantial reductions in subcontractor related expenses were partially offset by a slight rise in salary and related expenses. Materials and other expenses were relatively stable;
- Selling, general and administrative expenses rose 29% to $3.7 million vs $2.8 million. The increase was related to higher salary and related expenses due to one-time cash bonuses;
- Net financial income was $0.2 million compared to a net financial expense of ($0.4) million due greater contributions from interest income;
- Income taxes of $0.1 million compare to nil;
- Net loss was ($1.9) million vs ($3.6) million, or ($0.02) per share versus ($0.07) per share;

Cash and equivalents balance on September 30, 2023 totaled $41.0 million versus $22.2 million at the end of 2022. Cash burn was ($5.9) million for the first nine months of the year. Financing cash flows were $10.4 million predominantly related to proceeds from issuance of common stock through an at-the-market (ATM) facility. Other cash contributions came from the $20 million milestone paid by Chiesi. We do not anticipate the need to raise capital in at least the next 12 months and perhaps for a substantially longer period depending on Elfabrio's growth trajectory.

Appointment of New Chairman

Protalix announced the appointment of a new Chairman of its Board of Directors, Dr. Eliot Richard Forster. Dr. Forster serves on other boards as well including that of Avacta Group, Immatics NV and Ochre Bio. He was previously CEO of F-Star Therapeutics which was acquired by inovoX in March 2023. He has also been CEO of Immunocure, Creabilis and Solace Pharmaceuticals. Dr. Forster's big pharma background includes Pfizer and GlaxoWellcome.

Dr. Forster replaces Zeev Bronfeld who had served as Chairman of Protalix' board since August 2019. Mr. Bronfeld had served as a director of Protalix since 1996 and will retire as Dr. Forster assumes the post.

Scientific Presentations & Publications

During the third quarter of 2023 and to date, Protalix team members and related parties contributed to publications and presented data related to the Elfabrio (pegunigalsidate alfa) trials. In late August, the journal Genetics in Medicine published an article disclosing six-year results from the Phase I/II clinical trial of Elfabrio. Its title is "Long-term safety and efficacy of pegunigalsidase alfa: A multicenter 6-year study in adult patients with Fabry disease." The article was authored by Dr. Derralynn Hughes of University College London in London, who served as a principal investigator in PRX-102 clinical trials.

Protalix' Vice President, Research & Development, Yael Hayon, Ph.D., gave a presentation at the Next Generation Protein Therapeutics Summit in Boston. The event was held at the Boston Convention and Exhibition Center from September 18th to 20th.

The Orphanet Journal of Rare Disease published an article entitled "Safety and efficacy of pegunigalsidase alfa in patients with Fabry disease who were previously treated with agalsidase alfa: results from BRIDGE, a phase 3 open-label study." It was published online and authored by Ales Linhart, MD, Charles University, Praha, Czech Republic, a principal investigator in Protalix' clinical trials of PRX-102.

PRX-115

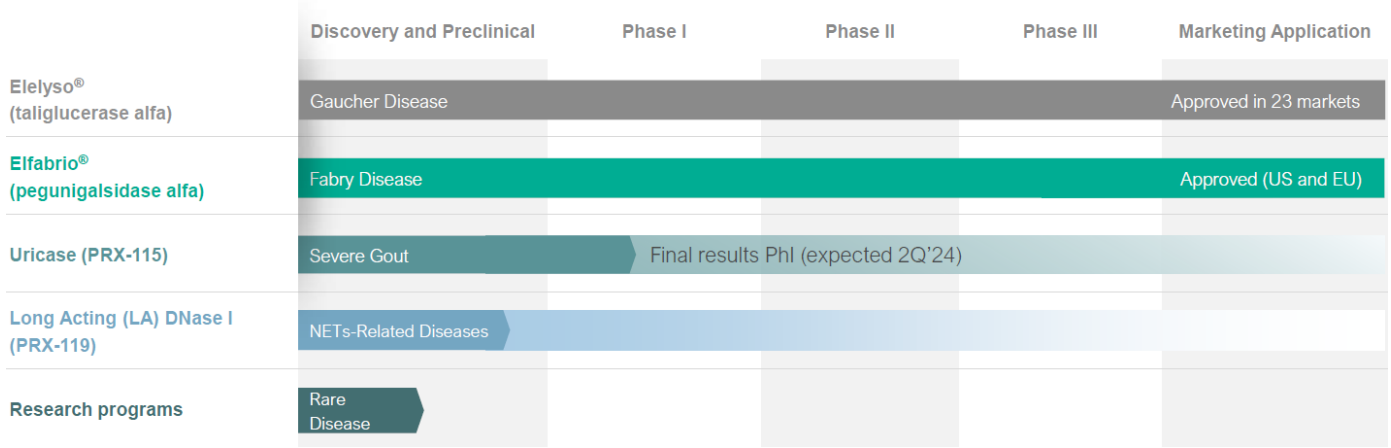
In March 2023, Protalix announced that it had dosed its first patient in the Phase I clinical trial for PRX-115 in the treatment of severe gout. The trial is designed as a double-blind, placebo-controlled, single ascending dose study intended to evaluate the safety and pharmacokinetics, pharmacodynamics and immunogenicity of PRX-115. Subjects considered for enrollment will present elevated uric acid levels (>6.0 mg/dL) and no previous exposure to PEGylated uricase. The single ascending dose study will have up to seven cohorts with patients randomized 3:1 to receive a single intravenous dose of PRX-115 or placebo. Other secondary endpoints will examine the reduction in uric acid and dosing efficacy. The study is being conducted at New Zealand Clinical Research under the New Zealand Medicines and Medical Devices Safety Authority. Further details on the clinical trial can be found on clinicaltrials.gov and the related entry under NCT05745727.

As of early November, and announced on the conference call, 42 subjects have been dosed in the trial and a total of 56 subjects are expected to be enrolled.[1] The trial is slated to be complete by early 2024. Final results are anticipated in mid-2024.

PRX-119

PRX-119 is the plant cell-expressed PEGylated recombinant human DNase I product candidate being designed to elongate half-life in the circulation of the molecule for NETs-related diseases. Protalix has conducted preclinical studies to evaluate the feasibility of the candidate and expects to continue compiling preclinical information and conducting data analysis to review with stakeholders. If signs are favorable, Protalix will conduct toxicology and Phase I studies. We expect to hear future details on the direction of the program in 2024.

Exhibit II – Protalix Pipeline[2]



[1] Note that the press release and Form 10-K report that 32 participants were enrolled as of September 30, 2023.
[2] Source: Protalix Corporate Presentation, August 2023

Milestones

- PRX-115 starts Phase I – 1Q:23
- EMA authorization for PRX-102 – May 5th, 2023
- FDA approval for PRX-102 – May 9th, 2023
- Investor event: Protalix Strategy – late June 2023
- Elfabrio approval in Switzerland – August 2023
- Elfabrio approval in Great Britain – September 2023
- Appointment of Richard Forster, Ph.D. as Chairman – September 2023
- Presentation at HC Wainwright Global Investment Conference – September 13, 2023
- PRX-115 Clinical Study Report – mid-year 2024

Summary

Protalix reported a quarter that generated better than expected product revenues and lower than expected expenses. However, we are still in the early days of ramp up and it is difficult to determine which revenues are ongoing and which are related to inventory building. Some positive signs are regulatory approval in two new jurisdictions and the recognition of $6.4 million in Elfabrio revenues that occurred after the end of the quarter, at the beginning of October. Our attention shifts to areas where Protalix has operational control, which is over the two leading development programs for gout (PRX-115) and NETs-related diseases (PRX-119). The gout trial is 75% enrolled and should provide topline results next year at which time we may see further studies announced. PRX-119 remains in the consideration stage with ongoing work identifying support for moving into the clinic.

We are optimistic on performance for Elfabrio and have confidence that Chiesi will accomplish an effective launch. With early regulatory successes in the UK and Switzerland, we hope to see other attractive markets such as Canada, Australia and Japan be announced as having granted approval in upcoming quarters. Chiesi offers a portfolio of multiple rare disease products and is well versed in the process of commercializing assets in this niche. Protalix' low valuation and substantial opportunity make this one of our most attractive names. We see Protalix as a tremendous value, holding sufficient cash to make it through the next year and providing a low risk of dilution for tenacious shareholders. Reward to risk is very favorable for equity investors. We maintain our valuation of $16 per share.

PROJECTED FINANCIALS

Protalix BioTherapeutics, Inc. - Income Statement[3]

Protalix Biotherapeutics	2022 A	Q1 A	Q2 E	Q3 A	Q4 E	2023 E	2024 E	2025 E
Total Revenues ($US '000)	**$47,638**	**$9,588**	**$35,075**	**$10,345**	**$10,450**	**$65,458**	**$74,060**	**$127,350**
YOY Growth	24%	-40%	301%	-27%	21%	37%	13%	72%
Cost of Revenues	$19,592	$3,085	$6,148	$4,893	$4,180	$25,894	$18,605	$19,300
Research & Development	$29,349	$5,847	$4,475	$3,669	$3,750	$17,741	$20,300	$19,500
Selling, General & Admin	$11,711	$3,115	$4,031	$3,670	$3,331	$14,147	$14,571	$15,009
Income from operations	($13,014)	($2,459)	$20,421	($1,887)	($811)	$7,676	$20,584	$73,542
Operating Margin	-27%	-26%	58%	-18%	-8%	12%	28%	
Financial Expenses	$2,529	$649	$1,305	$460	$650	$3,064	$2,600	$2,600
Financial Income	($1,146)	($172)	($531)	($628)	$0	($200)	$0	$0
Pre-Tax Income	($14,397)	($2,936)	$19,647	($1,719)	($1,461)	$4,812	$17,984	$70,942
Provision for Income Tax	$530	$195	$308	$133	$0	$636	$0	$0
Tax Rate	-3.7%	0.0%	0.0%	0.0%	0.0%	13.2%	0.0%	
Net Income	**($14,927)**	**($3,131)**	**$19,339**	**($1,852)**	**($1,461)**	**$4,176**	**$17,984**	**$70,942**
Net Margin	-31%	-33%	55%	-18%	-14%	6%	24%	56%
Reported EPS	**($0.31)**	**($0.05)**	**$0.21**	**($0.02)**	**($0.02)**	**$0.05**	**$0.21**	**$0.81**
Diluted Shares Outstanding	48,472	57,480	83,201	83,783	85,220	77,421	86,000	87,250

Source: Company Filing // Zacks Investment Research, Inc. Estimates

[3] Financial statement information presents data as originally reported.

HISTORICAL STOCK PRICE

Protalix BioTherapeutics, Inc. – Share Price Chart[4]

[4] Source: Zacks Research System

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